K101491

510(k) Summary
For
UROSKOP Omnia

JUN 30 2010

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

May 27, 2010

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **General Information**

Importer / Distributor
Siemens Medical Solutions, Inc.
51 Valley Stream Parkway, E-50
Malvern, PA 19355
Establishment Registration Number
2240869

Manufacturing Site
SIEMENS AG Sector Healthcare
Röntgenstr. 19 – 21
95478 Kemnath, Germany

2. **Contact Person**
Mr. Gary Johnson
Sr. Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway G-01
Malvern, PA 19355
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3. **Device Name and Classification**

Trade Name:	UROSKOP Omnia
Classification Name:	Solid state x-ray imager (flat panel/digital imager)
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1650
Device Class:	Class II
Device Code:	90 MQB

4. Device Description

UROSKOP Omnia is a radiographic and fluoroscopy examination table with the X-ray tube over the table and the detector underneath the patient table. The table top can be moved longitudinally and laterally as well as vertically.

This system is a modified version of the UROSKOP U04 (marketed as UROSKOP Access). The modification features a solid state image detector with the Fluorospot Compact in place of the Image Intensifier and CCD camera for image recording and processing. The table design remains unchanged while the new imaging chain is based on the AXIOM Luminos dRF described in premarket notification K 062623 which received FDA Clearance on August 22. 2007.

5. Intended Use

The UROSKOP Omnia is a solid state detector fluoroscopic X-ray system, primarily for urological applications (functional x-ray diagnostics, endourology and minimal invasive urology/surgery). The system, which includes a radiologic/urologic treatment table, may be used for urological, gastroenterological and gynecological treatment, planning and diagnostic procedures including but not limited to:

- Querying and retrieving patient history information and/or previous diagnosis and images from other modalities.
- X-ray examinations of the urogenital area (e.g. cystoscopy, kidney, bladder, ureter, urethra) including KUB, IVP, vasovesiculography, reflux-cystogram, cystourethrogram, and micturation cystourethrogram combined with uroflow measurements.
- Ultrasound examinations (in conjunction with a stand-alone ultrasound system) of the kidney, bladder, prostate, scrotum.
- endourological interventions (e.g. of the urethra, prostate, bladder, sphincter, ostium, kidney and ureter, catheter placement, penile implant placement, transurethral resection of prostate or bladder, alternative treatment of the BPH, brachytherapy, as well as gynecological procedures requiring radiological support).
- percutaneous interventions (e.g. PCN nephrolithotomy, resection, percutaneous nephrostomy)
- laparoscopy (e.g. cholecystectomy, nephrectomy, lymph node dissection, abdominal testis detection/correction, varicocele).
- application of fistula (kidney/bladder)
- simple procedures (e.g. urethra, testis, phimosis)
- intracorporeal shock wave lithotripsy
- uroflow/urodynamics
- pediatric radiological and therapeutic applications.

6. **Substantial Equivalence**

The UROSKOP Omnia with Flat Detector is substantially equivalent to the commercially available Siemens systems, the UROSKOP U04 and the AXIOM Luminos dRF. The UROSKOP U04 was described in premarket notification K 010942 which received FDA Clearance on April 12, 2001. The AXIOM Luminos dRF was described in premarket notification K.062623 which received FDA Clearance on August 22. 2007.

X-ray generation and control used with the UROSKOP Omnia is identical to the AXIOM Luminos dRF. The Flat Detector Pixium 5100 and the Fluorospot Compact digital imaging system equipped with UROSKOP Omnia are identical to the detector and imager used in the AXIOM Luminos dRF.

7. **Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device**

UROSKOP Omnia is a modified UROSKOP U04. The principal device UROSKOP Omnia features a solid state detector instead of an x-ray image intensifier like the predicate UROSKOP U04. The design of the UROSKOP Omnia's imaging chain is based on the design of the second predicate the AXIOM Luminos dRF. Also the Omnia shares the same x-ray- and software components with the Luminos. (Table base, Generator, X-ray tube and housing, beam-limiting-devise flat detector, digital image processing device, etc.)
Many of these components used in UROSKOP Omnia are either commercially available with current Siemens systems or include minor modifications to existing components.

8. **General Safety and Effectiveness Concerns**

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design. In addition the UROSKOP Omnia is continually monitored, and if an error occurs, the system functions will be blocked and an error message will be displayed.
Furthermore the operators are health care professionals familiar with and responsible for the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

9. **Conclusion as to Substantial Equivalence**

The UROSKOP Omnia is intended for the same indications for use as the predicate UROSKOP U04. The imaging chain has been modified to include a flat panel detector and the Fluorospot Compact, a digital imaging system. The potfolio of accessories are the same as with the predicate UROSKOP U04 to compliment the needs of the Urology suite. It is Siemens opinion, that the UROSKOP Omnia is substantially equivalent to the UROSKOP U04.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Gary Johnson
Senior Regulatory Technical Specialist
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway G-01
MALVERN PA 19355-1406

AUG 21 2013

Re: K101491
Trade/Device Name: UROSKOP Omnia
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA and MQB
Dated: May 27, 2010
Received: June 1, 2010

Dear Mr. Johnson:

This letter corrects our substantially equivalent letter of June 30, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

SECTION 4

INDICATIONS FOR USE

510(k) Number (if known): K101491

Device Name: UROSKOP Omnia

Indications for Use:

The UROSKOP Omnia is a solid state detector fluoroscopic X-ray system, primarily for urological applications (functional x-ray diagnostics, endourology and minimal invasive urology/surgery). The system, which includes a radiologic/urologic treatment table, may be used for urological, gastroenterological and gynecological treatment, planning and diagnostic procedures including:

- Querying and retrieving patient history information and/or previous diagnosis and images from other modalities.
- X-ray examinations of the urogenital and area (e.g. cystoscopy, kidney, bladder, ureter, urethra) including KUB, IVP, vasovesiculography, reflux-cystogram, cystourethrogram, and micturation cystourethrogram combined with uroflow measurements.
- Ultrasound examinations (in conjunction with a stand-alone ultrasound system) of the kidney, bladder, prostate, scrotum.
- endourological interventions (e.g. of the urethra, prostate, bladder, sphincter, ostium, kidney and ureter, catheter placement, penile implant placement, transurethral resection of prostate or bladder, alternative treatment of the BPH, brachytherapy, as well as gynecological procedures requiring radiological support).
- percutaneous interventions (e.g. PCN nephrolithotomy, resection, percutaneous nephrostomy)
- laparoscopy (e.g. cholecystectomy, nephrectomy, lymph node dissection, abdominal testis detection/correction, varicocele).
- application of fistula (kidney/bladder)
- simple procedures (e.g. urethra, testis, phimosis)
- intracorporeal shock wave lithotripsy
- uroflow/urodynamics
- pediatric radiological and therapeutic applications.

Prescription Use _____ OR Over-The-Counter Use _____
(per 21 CFR 801.109)

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Concurrence of the CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101491